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UNITED STATES DISTRICT COURT
CENTRAL DISTRICT OF CALIFORNIA

IN RE: BOSTON SCIENTIFIC
CORPORATION SPINAL CORD
STIMULATOR PRODUCTS
LIABILITY LITIGATION

Case No. 2:26-ml-03181-JLS-PD

Hon. Josephine L. Staton

This Document Relates To:
APA TRACK ONLY
ALL ACTIONS

**CONSOLIDATED MASTER APA
COMPLAINT FOR DECLARATORY
AND INJUNCTIVE RELIEF UNDER
THE ADMINISTRATIVE
PROCEDURE ACT**

1 Plaintiffs, by and through Plaintiffs' Co-Lead Counsel, bring this Consolidated
2 APA Complaint, filed pursuant to Pretrial Order No. 5 (Dkt. 68) ("PTO 5"), against
3 Defendants the United States Food and Drug Administration ("FDA"), the
4 Commissioner of Food and Drugs, and the Secretary of Health and Human Services
5 (the latter two, the "Officer Defendants," and together with the FDA, "Defendants")
6 under the Administrative Procedure Act ("APA"), 5 U.S.C. §§ 701-706. This Court
7 has subject-matter jurisdiction under 28 U.S.C. § 1331. Plaintiffs allege as follows,
8 upon personal knowledge as to themselves and their own acts and, as to all other
9 matters, upon information and belief, including the investigation of counsel and review
10 of the FDA's public records.

11 I. NATURE OF THE ACTION

12 1. This consolidated action challenges the FDA's 2004 grant of Premarket
13 Approval ("PMA") No. P030017 for the Precision Spinal Cord Stimulator System
14 ("Precision System"), as well as subsequent PMA modifications and approvals. Boston
15 Scientific Corporation and Boston Scientific Neuromodulation Corporation
16 (collectively, "Boston Scientific") have built their entire line of spinal cord stimulator
17 ("SCS") devices, including the devices implanted in Plaintiffs, on that approval.

18 2. Plaintiffs challenge the original approval on two independent grounds: (a)
19 the FDA substituted a finding of sufficient similarity to other devices for the device-
20 specific safety-and-effectiveness determination the statute requires, effectively
21 applying a lower standard than that needed even for approval of a 510(k) device, much
22 less a PMA device, and (b) independently, the FDA failed to provide a reasoned
23 explanation and to address important aspects of device safety and effectiveness.
24 Plaintiffs also challenge the identified supplement orders, both as derivative of the
25 unlawful 2004 approval and independently of it, in addition and in the alternative.
26 Plaintiffs seek the declaratory, injunctive, vacatur, and remand relief specified in each
27 count.
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1 3. Congress reserved Premarket Approval, the most rigorous form of federal
2 medical device review, for the highest-risk Class III devices, and conditioned it on a
3 specific statutory showing: the FDA must deny approval absent "a showing of
4 reasonable assurance that such device is safe" and "that the device is effective" under
5 the conditions of use in its proposed labeling. 21 U.S.C. §§ 360c(a)(2)–(3), 360e(d)(1)–
6 (2). That condition protects patients from exposure to high-risk devices whose
7 expected benefits have not been adequately established and weighed against their risks.

8 4. The FDA did not lawfully make that finding when it approved PMA
9 P030017. Although the agency recited the statutory standard, it did not ground that
10 recital in valid scientific evidence concerning the device submitted for approval. By
11 the agency's own account in its Summary of Safety and Effectiveness Data ("SSED"),
12 the approval of the Precision System rested on "available peer reviewed published
13 literature for similar implantable spinal cord stimulation (SCS) systems," that is, on
14 clinical studies of *other manufacturers' devices*, because the agency concluded the
15 Precision System was "sufficiently similar to the SCS systems reported in literature."¹
16 The only clinical data concerning the Precision System itself reported only adverse
17 events and charging usability in 26 implanted patients, and no effectiveness results.

18 5. "Sufficiently similar" is a lower standard even than that needed for
19 approval through the 510(k) substantial-equivalence pathway, under which a device
20 may reach the market without any showing of its own safety and effectiveness because
21 the FDA finds it "substantially equivalent" to a device that does not require Premarket
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26 ¹ FDA, *Summary of Safety and Effectiveness Data: PRECISION™ Spinal Cord*
27 *Stimulator System*, PMA No. P030017 (Apr. 27, 2004),
https://www.accessdata.fda.gov/cdrh_docs/pdf3/P030017b.pdf.
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1 Approval.² It is certainly not the standard for a device that, like the Precision System,
2 must obtain Premarket Approval.

3 6. The PMA pathway instead requires a supported safety-and-effectiveness
4 determination for the device submitted for approval. A finding that a device is
5 sufficiently similar to other systems cannot substitute for that determination, and
6 evidence concerning other systems can contribute to it only through a reasoned
7 scientific connection between that evidence and the safety and effectiveness of the
8 device approved. FDA failed in both respects: it treated similarity as a substitute for
9 the required determination, and it failed to supply the connection that any permissible
10 reliance on other systems' evidence would have required. In doing so, the FDA acted
11 arbitrarily, capriciously, in excess of its statutory authority, and otherwise not in
12 accordance with law. 5 U.S.C. § 706(2)(A), (C), (D).

13 7. In 2001, when the FDA denied a manufacturer's petition to reclassify
14 totally implantable SCS systems as Class II devices, the FDA determined that "special
15 controls, such as bench and animal testing, cannot substitute for actual clinical trials
16 designed to demonstrate the safety and effectiveness of these devices." 66 Fed. Reg.
17 21,401, 21,402 (Apr. 30, 2001).³ Three years later and contrary to its own standard, the
18 FDA approved the Precision System based on literature about other devices combined
19 with bench and animal testing, without acknowledging or explaining that reversal.
20 FDA's approval of P030017, which used methods that failed to meet the threshold
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23 ² See FDA, *The 510(k) Program: Evaluating Substantial Equivalence in Premarket*
24 *Notifications [510(k)]: Guidance for Industry and Food and Drug Administration*
25 *Staff* (July 28, 2014), <https://www.fda.gov/media/82395/download>; see also 21
26 U.S.C. § 360c(i).

27 ³ Neurological Devices; Reclassification of the Totally Implanted Spinal Cord
28 Stimulator; Denial of Petition, 66 Fed. Reg. 21,401 (Apr. 30, 2001),
<https://www.govinfo.gov/content/pkg/FR-2001-04-30/pdf/01-10619.pdf>.

1 criteria noted in the reclassification denial, lacked a reasoned explanation of its
2 decision.

3 8. Through successive supplements, FDA then authorized changes in
4 stimulation delivery, programming, leads, and device architecture. The challenged
5 decisions carried forward an inadequate evidentiary foundation, approved substantial
6 redesigns through supplement pathways that Congress reserved for lesser changes, and
7 failed to establish that the evidence remained sufficient for the changed devices and
8 uses. Of the more than 370 supplements the FDA has approved, only three were
9 reviewed as panel-track supplements, and those only expanded the devices' indications
10 for use. Plaintiffs seek enforcement of the statutory approval conditions through
11 judicial review of these completed decisions.

12 9. Plaintiffs are patients who were implanted with these devices. For most
13 Plaintiffs, the devices have not relieved their pain, have caused new injuries, and have
14 required removal, resulting in pain, suffering, and economic losses. For some
15 Plaintiffs, despite their ineffectiveness and having caused additional injuries, these
16 devices remain implanted because Plaintiffs cannot afford the surgery to remove them.
17 Section V.G describes those circumstances.

18 10. Plaintiffs do not ask this Court to second-guess the FDA's scientific
19 expertise or to make the safety and effectiveness determination that the statute assigns
20 to the agency. Plaintiffs ask that the Court hold the 2004 approval unlawful because
21 the FDA failed to follow its own standards and the approval did not satisfy the statutory
22 prerequisites for a PMA. Plaintiffs thus ask the Court to set that approval aside under
23 5 U.S.C. § 706(2), and remand so that the agency makes that determination under the
24 standard Congress prescribed and the FDA's own regulations require.

25 11. The challenged approvals cause concrete injury to Plaintiffs. They
26 authorize the devices and features associated with Plaintiffs' ongoing physical and
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1 economic injuries and supply the regulatory predicates Boston Scientific invokes to
2 defeat Plaintiffs' state-law claims.

3 12. The relief Plaintiffs seek provides redress for those concrete and ongoing
4 injuries. Vacatur and remand would require the FDA to decide anew, under the correct
5 standard, whether those devices may lawfully remain on the market and whether
6 patients are entitled to notification, repair, replacement, or refund. 21 U.S.C. §§
7 360e(e), 360h. Vacatur would also remove the legal predicate for the federal
8 preemption defense that Boston Scientific has asserted in member actions as a
9 complete bar to the state-law claims of patients injured by its SCS devices.

10 II. JURISDICTION AND VENUE

11 13. This action arises under the Administrative Procedure Act, 5 U.S.C. §§
12 701-706, and the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301
13 *et seq.*, including the Medical Device Amendments of 1976 ("MDA"), 21 U.S.C. §
14 360c *et seq.*

15 14. This Court has subject-matter jurisdiction under 28 U.S.C. § 1331 because
16 this action arises under the laws of the United States, including 5 U.S.C. § 706. Sections
17 702 and 704 of the APA authorize Plaintiffs, who are adversely affected by the
18 identified final agency actions, to obtain judicial review of those actions. To the extent
19 Plaintiffs seek to compel agency action unlawfully withheld, the Court also has
20 jurisdiction under 28 U.S.C. § 1361.

21 15. The APA waives the FDA's sovereign immunity for the relief sought here:
22 an action "seeking relief other than money damages" and "stating a claim that an
23 agency or an officer or employee thereof acted or failed to act." 5 U.S.C. § 702.
24 Plaintiffs seek only declaratory and injunctive relief, not monetary damages, against
25 the FDA.

26 16. Venue is proper in this District under 28 U.S.C. § 1391(e)(1)(B) because
27 a substantial part of the events giving rise to the claims occurred here, as alleged below.
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17. Advanced Bionics Corporation prepared and submitted the PMA application for P030017 from its facilities at 12740 San Fernando Road, Sylmar, California, in Los Angeles County. See SSED § I (Exhibit A); Approval Order at 1 (Exhibit B). Boston Scientific's neuromodulation business, which holds PMA P030017 and has prepared and submitted its supplements, is headquartered in this District at 25155 Rye Canyon Loop, Valencia, California. *See* Transfer Order at 6 (noting that "Boston Scientific's neuromodulation division is headquartered in this district").⁴ Upon information and belief, Boston Scientific Neuromodulation is registered with the FDA, through that facility, as the specification developer for these systems, responsible for their design validation and corrective and preventive actions. The FDA's PMA database identifies Boston Scientific Corp., 25155 Rye Canyon Loop, Valencia, California, as the applicant for PMA P030017 and for each of Supplements S100, S134, S235, S271, and S338. The submissions that produced the challenged approvals therefore originated in this District.

18. This Court has authority to enter the declaratory and injunctive relief requested under 5 U.S.C. § 706, 28 U.S.C. §§ 2201-2202, and Federal Rules of Civil Procedure 57 and 65.

III. PARTIES

A. Plaintiffs

19. Plaintiffs are individuals in whom Boston Scientific SCS devices marketed under PMA P030017 and its supplements were implanted, and who filed member actions in this MDL asserting APA claims against the FDA.⁵ A complete list

⁴ Transfer Order at 6, *In re: Boston Scientific Corp. Spinal Cord Stimulator Prods. Liab. Litig.*, MDL No. 3181, ECF No. 76 (J.P.M.L. June 5, 2026), https://www.jpml.uscourts.gov/sites/jpml/files/MDL-3181-Transfer_Order-5-26.pdf.

⁵ See, e.g., Complaint, *Albright v. Boston Scientific Corp.*, No. [2:26-cv-12268] (C.D. Cal. filed Oct. 20, 2026) ("*Albright* Compl."); Complaint, *Bayhi v. Boston Scientific Corp.*, No. [2:26-cv-12269] (C.D. Cal. filed Oct. 20, 2026) ("*Bayhi* Compl.");

of known Plaintiffs with filed claims against the FDA in this MDL is attached hereto as Exhibit C. Each of those Plaintiffs is a named plaintiffs for purposes of this Consolidated Complaint. Additional plaintiffs who assert APA claims against the FDA may later adopt this Consolidated APA Complaint, as described below.

20. Each Plaintiff's individual allegations, including the Plaintiff's device, implant history, and injuries, are set forth in that Plaintiff's individual or short-form complaint.

21. This Consolidated APA Complaint is the operative pleading for the consolidated APA claims against the FDA in this MDL and, upon filing, supersedes and replaces the APA claims against the FDA pleaded in the individual complaints of each Plaintiff identified in Section III, except as to Plaintiff-specific allegations. PTO 5 ¶ 3. Those claims will be litigated exclusively through this pleading, which "shall not be merely an administrative device" but is "the legally operative pleading and the operative unit for purposes of motion practice, adjudication, entry of judgment, and appeal." *Id.*

22. The claims asserted herein proceed on a separate procedural track from the product-liability claims against Boston Scientific. PTO 5 ¶ 4. Any plaintiff who later adopts this Consolidated APA Complaint, whether by a short-form complaint or by an individual complaint filed in or transferred to this Court, will be treated as a Plaintiff herein and bound by the rulings on it. *Id.* ¶¶ 7-8. Those Plaintiffs' individual facts are alleged in their short-form or individual complaints.

B. Defendants

23. **Defendant United States Food and Drug Administration** is an agency of the United States government within the Department of Health and Human Services.

Complaint, *Lamy v. Boston Scientific Corp.*, No. [2:26-cv-12271] (C.D. Cal. filed Oct. 20, 2026) ("*Lamy Compl.*"); Complaint, *Robinette v. Boston Scientific Corp.*, No. [2:26-cv-12272] (C.D. Cal. filed Oct. 20, 2026) ("*Robinette Compl.*").

1 The FDA is charged with administering the FDCA and the MDA, including the
2 premarket-approval program for Class III medical devices, 21 U.S.C. § 360e. The FDA
3 is sued solely in its official capacity for declaratory and injunctive relief under the
4 APA. No claim for money damages is asserted against the FDA.

5 **24. Defendant Kyle Diamantas, Acting Commissioner of Food and Drugs**
6 **(“Commissioner”)**, heads the FDA and is responsible for the agency's administration
7 of the FDCA and the MDA, including the premarket-approval program for Class III
8 devices. *See* 21 U.S.C. § 393(d). The Commissioner is sued in an official capacity
9 only.⁶

10 **25. Defendant Robert F. Kennedy, Jr., Secretary of Health and Human**
11 **Services (“Secretary”)**, heads the Department of Health and Human Services, of
12 which the FDA is a part, and in whom the FDCA vests the authority the FDA exercises
13 in granting, maintaining, and withdrawing Premarket Approval. 21 U.S.C. §§ 360e,
14 393. The Secretary is sued in an official capacity only.⁷

15 26. The Officer Defendants are named so that any mandatory or injunctive
16 decree may specify the federal officers personally responsible for compliance. 5 U.S.C.
17 § 702. References in this Consolidated APA Complaint to the “FDA” or the “agency”
18 include the Officer Defendants unless the context indicates otherwise.

19 **C. Boston Scientific**

20 27. Boston Scientific is not a defendant to this Consolidated APA Complaint.
21 The products-liability claims against Boston Scientific are pleaded in the separate
22 Master Complaint in the personal-injury track of this MDL. Boston Scientific is
23 identified here because the devices implanted in Plaintiffs were marketed under PMA
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25 ⁶ *See* FDA, *Kyle Diamantas*, [https://www.fda.gov/about-fda/fda-organization/kyle-](https://www.fda.gov/about-fda/fda-organization/kyle-diamantas)
26 [diamantas](https://www.fda.gov/about-fda/fda-organization/kyle-diamantas).

27 ⁷ *See* U.S. Dep't of Health & Hum. Servs., *Robert F. Kennedy, Jr.*,
28 <https://www.hhs.gov/about/leadership/robert-kennedy.html>.

1 P030017 and its supplements, the approvals on which Boston Scientific relies for its
2 preemption defense.

3 28. Pursuant to PTO 5 ¶ 5, Boston Scientific Corporation and Boston
4 Scientific Neuromodulation Corporation are treated as intervenor-defendants with
5 respect to the claims asserted herein for purposes of a motion to dismiss and any related
6 appeal and may participate in other proceedings by agreement or with leave of Court.
7 Consistent with PTO 5 ¶ 2, no product-liability or other claim against Boston Scientific
8 is asserted in this pleading.

9 29. PMA P030017 was originally granted to Advanced Bionics Corporation
10 for the Precision Spinal Cord Stimulator System. Boston Scientific acquired Advanced
11 Bionics Corporation in 2004.⁸ Boston Scientific's spinal cord stimulation business, now
12 operated through Boston Scientific Neuromodulation Corporation, is the successor to
13 Advanced Bionics' spinal cord stimulation business, and Boston Scientific is the
14 present holder of PMA P030017 and its supplements.

15 IV. STATUTORY AND REGULATORY FRAMEWORK

16 A. Premarket Approval

17 30. The MDA classifies medical devices into three classes based on risk.
18 Class III devices, which support or sustain human life, substantially prevent
19 impairment of health, or pose an unreasonable risk of illness or injury, are subject to
20 the most rigorous oversight. 21 U.S.C. § 360c(a)(1)(C).

21 31. A Class III device may not be marketed unless the FDA grants Premarket
22 Approval. 21 U.S.C. § 360e(a). Implantable spinal cord stimulators are Class III
23 devices requiring Premarket Approval. *See* 66 Fed. Reg. at 21,401.

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26 ⁸ *See* Press Release, Boston Scientific, *Boston Scientific Announces Acquisition of*
27 *Advanced Bionics Corporation*, [https://news.bostonscientific.com/acquisition-](https://news.bostonscientific.com/acquisition-advanced-bionics-corporation)
28 [advanced-bionics-corporation](https://news.bostonscientific.com/acquisition-advanced-bionics-corporation).

32. Premarket Approval is a "rigorous" process. *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 317 (2008). It stands in deliberate contrast to the far less demanding 510(k) "premarket notification" pathway, under which a new device may be marketed without premarket approval if the FDA finds it "substantially equivalent" to a device exempt from premarket approval. *Id.* Substantial equivalence to another device is not a permissible substitute for the device-specific safety and effectiveness finding that Premarket Approval requires.

33. The FDA must deny Premarket Approval if there is "a lack of a showing of reasonable assurance that such device is safe" or "that the device is effective" under the conditions of use in its proposed labeling. 21 U.S.C. § 360e(d)(2)(A)-(B). The FDA is supposed to grant approval only if it finds a "reasonable assurance" of the device's "safety and effectiveness." *Riegel*, 552 U.S. at 318. The statutory assurance runs to "such device," the specific device for which approval is sought, not to a different device the agency regards as comparable.

34. The statute also prescribes how effectiveness must be shown. A device's effectiveness is to be determined "on the basis of well-controlled investigations, including 1 or more clinical investigations where appropriate," by experts qualified to evaluate the device, from which it can fairly and responsibly be concluded that the device will have the effect it purports or is represented to have. 21 U.S.C. § 360c(a)(3)(A). The agency may accept other valid scientific evidence only where that evidence is itself sufficient for qualified experts to reach that conclusion about the device under review. *Id.* § 360c(a)(3)(B).

35. The FDA's own regulations are to the same effect. Valid scientific evidence of effectiveness "shall consist principally of well-controlled investigations" unless the agency authorizes reliance on other valid scientific evidence. 21 C.F.R. § 860.7(e)(2). "Isolated case reports, random experience, reports lacking sufficient

1 details to permit scientific evaluation, and unsubstantiated opinions are not regarded as
2 valid scientific evidence to show safety or effectiveness." *Id.* § 860.7(c)(2).

3 36. The FDA's regulation defining "valid scientific evidence," 21 C.F.R. §
4 860.7(c)(2), permits the agency to consider well-documented case histories and reports
5 of significant human experience "with a marketed device." Even then, the evidence
6 qualifies only if it is evidence "from which it can fairly and responsibly be concluded
7 by qualified experts that there is reasonable assurance of the safety and effectiveness
8 of a device under its conditions of use." *Id.* That regulation does not authorize the FDA
9 to approve a new, unmarketed Class III device on the strength of literature about a
10 different marketed device in lieu of evidence of the subject device's own safety and
11 effectiveness. To the extent the FDA relies on experience with other systems as part of
12 the basis for approval, that evidence must support the inference to the subject device.
13 Differences in design, manufacture, performance, and clinical use that bear on the
14 inference must be addressed. An unsupported assertion of comparability does not
15 establish the assurance Congress required.

16 37. In approving PMA P030017, the FDA cited the "least burdensome"
17 provision added by section 205 of the Food and Drug Administration Modernization
18 Act of 1997. That provision did not relax the substantive standard for Premarket
19 Approval. As in effect in 2004, it applied when the agency specified, in advance of an
20 application, the evidence the applicant would need to submit, and it directed that "[t]he
21 Secretary shall consider, in consultation with the applicant, the least burdensome
22 appropriate means of evaluating device effectiveness that would have a reasonable
23 likelihood of resulting in approval." 21 U.S.C. § 360c(a)(3)(D)(ii) (2000 & Supp. II
24 2002) (added by Pub. L. No. 105-115, § 205(a), 111 Stat. 2296, 2336-37 (1997)). It
25 left untouched the requirement that effectiveness be determined on the basis of well-
26 controlled investigations or other valid scientific evidence sufficient to support the
27 statutory conclusion. *Id.* § 360c(a)(3)(A)-(B). When Congress later applied the least-
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1 burdensome principle to the FDA's requests for additional information on PMA
2 applications, it confirmed that "[n]othing in this paragraph alters the standards for
3 premarket approval of a device." 21 U.S.C. § 360e(c)(5)(D) (added by 21st Century
4 Cures Act, Pub. L. No. 114-255, § 3058(b) (2016)).

5 38. A PMA application must contain, among other things, "full reports of all
6 information, published or known to or which should reasonably be known to the
7 applicant, concerning investigations which have been made to show whether or not
8 such device is safe and effective." 21 U.S.C. § 360e(c)(1)(A). The FDA's regulations
9 separately require "[a] section containing results of the clinical investigations involving
10 human subjects with the device," 21 C.F.R. § 814.20(b)(6)(ii), and treat published
11 reports not submitted as such results as a distinct category, to be identified in a
12 bibliography, *id.* § 814.20(b)(8)(i).

13 **B. PMA Supplements**

14 39. After a PMA is granted, a change to the device affecting safety or
15 effectiveness is made through a PMA supplement, "evaluated under largely the same
16 criteria as an initial application." *Riegel*, 552 U.S. at 319; 21 C.F.R. § 814.39.

17 40. A supplement requesting a significant change in the design or
18 performance of a device, or a new indication for use, for which substantial clinical data
19 are necessary, is a "panel-track supplement." 21 U.S.C. § 379i(4)(B); *see* 21 C.F.R. §
20 814.39. A "180-day supplement," by contrast, is one that "is not a panel-track
21 supplement" and requests "a significant change in components, materials, design,
22 specification, software, color additives, or labeling." 21 U.S.C. § 379i(4)(C). The line
23 Congress drew thus turns on whether "substantial clinical data are necessary to provide
24 a reasonable assurance of safety and effectiveness." *Id.* § 379i(4)(B).

25 41. Congress also specified when the FDA must approve a supplement for an
26 incremental design change. For "an incremental change to the design of a device that
27 affects safety or effectiveness," the Secretary "shall approve such supplement if"
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1 "nonclinical data demonstrate that the design modification creates the intended
2 additional capacity, function, or performance of the device" and "clinical data from the
3 approved application and any supplement to the approved application provide a
4 reasonable assurance of safety and effectiveness for the changed device." 21 U.S.C. §
5 360e(d)(5)(B)(i)(I)-(II). The FDA "may require, when necessary, additional clinical
6 data to evaluate the design modification of the device to provide a reasonable assurance
7 of safety and effectiveness." *Id.* § 360e(d)(5)(B)(ii). The provision was added in 1997
8 as § 360e(d)(6), was redesignated as § 360e(d)(5) in 2016 without change to its text,
9 and was in effect when each challenged supplement was approved. Pub. L. No. 105-
10 115, § 205(c)(2), 111 Stat. 2296, 2338 (1997); Pub. L. No. 114-255, § 3051(c)(1)
11 (2016) (redesignating it as § 360e(d)(5)).

12 42. FDA's December 11, 2008 PMA Supplement Decision-Making Guidance
13 identifies the continued applicability of prior evidence as central to selecting the
14 appropriate submission. Its pacemaker lead example recognizes that a component
15 modification can warrant a traditional PMA even when the indication remains
16 unchanged. Guidance § IV.A(2).⁹

17 43. FDA's own regulation requires appropriate justification and supervisory
18 concurrence for a departure from its guidance. 21 C.F.R. § 10.115(d)(3). The agency's
19 selection of a supplement pathway therefore required a scientifically supported
20 application of its framework or an appropriately justified departure.

21 **C. The FDA's Continuing Authority After Approval**

22 44. The FDA's responsibilities do not end with approval. The Secretary must
23 withdraw approval of a PMA when new information, evaluated together with the
24 evidence available at approval, shows a lack of reasonable assurance that the device is

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26 ⁹ FDA, *Modifications to Devices Subject to Premarket Approval (PMA): The PMA*
27 *Supplement Decision-Making Process; Guidance for Industry and FDA Staff* (Dec.
28 11, 2008), <https://www.fda.gov/media/81431/download>.

1 safe or effective, and must temporarily suspend approval when continued distribution
2 presents a reasonable probability of serious adverse health consequences or death. 21
3 U.S.C. § 360e(e)(1), (3); 21 C.F.R. § 814.46. The FDA may also order notification,
4 repair, replacement, or refund, and may order a recall. 21 U.S.C. § 360h; 21 C.F.R. pt.
5 810. A Class III device without an approved PMA in effect is adulterated. 21 U.S.C. §
6 351(f)(1)(B).

7 **D. Judicial Review**

8 45. The APA empowers this Court to "hold unlawful and set aside agency
9 action, findings, and conclusions found to be" arbitrary, capricious, an abuse of
10 discretion, or otherwise not in accordance with law; contrary to constitutional right; in
11 excess of statutory jurisdiction or authority; or without observance of procedure
12 required by law. 5 U.S.C. § 706(2)(A)-(D). It also empowers the Court to "compel
13 agency action unlawfully withheld or unreasonably delayed." 5 U.S.C. § 706(1).

14 46. Under *Loper Bright Enterprises v. Raimondo*, 603 U.S. 369, 412-13
15 (2024), the APA requires courts to exercise their independent judgment in deciding
16 whether an agency has acted within its statutory authority; courts do not defer to an
17 agency's interpretation of the statute it administers. Whether the FDA complied with
18 21 U.S.C. § 360e(d) in granting PMA P030017 is a question of law for this Court to
19 decide without deference.

20 **V. FACTUAL ALLEGATIONS**

21 **A. The FDA's 2001 Determination That SCS Devices Require Clinical** 22 **Trials**

23 47. The FDA's approval of PMA P030017 also cannot be reconciled with the
24 agency's own earlier determination of what these devices require. On June 16, 1999,
25 Advanced Neuromodulation Systems petitioned the FDA to reclassify the totally
26 implanted spinal cord stimulator from Class III to Class II, where it could be cleared
27 through the 510(k) substantial-equivalence process. FDA Docket No. 00P-0788. The
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1 FDA's Neurological Devices Panel recommended reclassification at a September 16-
2 17, 1999 meeting, and the FDA published tentative findings agreeing with the Panel.
3 65 Fed. Reg. 54,053 (Sept. 6, 2000).¹⁰ On February 23, 2001, however, the FDA
4 reversed course and denied the petition. 66 Fed. Reg. 21,401 (Apr. 30, 2001). The FDA
5 explained that "[t]he most serious risk to health presented by the device is the risk of
6 device failure," that "[d]evice failure is frequently the result of improper device
7 design," and that "special controls, such as bench and animal testing, cannot substitute
8 for actual clinical trials designed to demonstrate the safety and effectiveness of these
9 devices." *Id.* at 21,402. The device therefore remained in Class III, subject to Premarket
10 Approval.

11 **B. The 2004 Approval of the Precision System**

12 48. Boston Scientific's entire SCS product line originates from, and is
13 predicated on, PMA P030017, which Advanced Bionics filed on May 14, 2003, and
14 which the FDA approved on April 27, 2004, for the Precision Spinal Cord Stimulator
15 System. Boston Scientific's SCS devices, including the Precision Plus, Precision
16 Spectra, Precision Montage, Precision Montage MRI, Spectra WaveWriter (also
17 marketed as Precision Spectra WaveWriter), Precision Novi, WaveWriter Alpha, and
18 WaveWriter Alpha Prime systems, together with the leads, extensions, and other
19 components marketed for use with them, all trace to PMA P030017 and its
20 supplements.

21 49. The SSED for PMA P030017, attached as Exhibit A, establishes that the
22 approval rested principally on evidence about other devices, not on clinical evidence
23 of the Precision System's own safety and effectiveness. The FDA's April 27, 2004,
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25 ¹⁰ Neurological Devices; Reclassification of the Totally Implanted Spinal Cord
26 Stimulator, 65 Fed. Reg. 54,053 (Sept. 6, 2000),
27 [https://www.federalregister.gov/documents/2000/09/06/00-22618/neurological-](https://www.federalregister.gov/documents/2000/09/06/00-22618/neurological-devices-reclassification-of-the-totally-implanted-spinal-cord-stimulator)
28 [devices-reclassification-of-the-totally-implanted-spinal-cord-stimulator](https://www.federalregister.gov/documents/2000/09/06/00-22618/neurological-devices-reclassification-of-the-totally-implanted-spinal-cord-stimulator).

1 approval order ("Approval Order"), attached as Exhibit B, itself describes the SSED as
2 "a summary of the safety and effectiveness data upon which the approval is based."
3 Approval Order at 2.¹¹

4 50. The SSED states, in its Summary of Clinical Studies: "The clinical data
5 summarized below was based on available peer reviewed published literature for
6 similar implantable spinal cord stimulation (SCS) systems." The three effectiveness
7 studies and eleven safety studies the agency relied upon examined *other* SCS systems,
8 not the Precision System. SSED § X. The SSED states that the "primary objective was
9 to provide clinical evidence of the effectiveness of the PRECISION™ System, using
10 literature articles." *Id.* § X.A. The Precision System itself "has not been marketed in
11 the United States or any foreign country." SSED § VII. The SSED acknowledged that
12 the safety "citations cover both IPG and RF systems," *id.* § X.C, meaning they included
13 radio-frequency systems powered by an external source, which the SSED itself lists as
14 an alternative to a totally implanted system like the Precision System, *id.* § VI.
15 Additionally, the SSED's adverse-event data came from a search of the FDA's MDR
16 and MAUDE databases limited to other SCS devices: "Itrel, Synergy, Genesis, Pisces,
17 Octad, Quattrode, Octrode and Cervitrode." *Id.* § X.D.

18 51. The only clinical data concerning the Precision System itself described in
19 the SSED came from an ongoing study in which, as of January 15, 2004, 35 subjects
20 had been enrolled and 26 implanted, with follow-up ranging from two weeks to six
21 months. SSED § X.E. The SSED reports only adverse events from that study, and no
22

23 ¹¹ Letter from FDA, Ctr. for Devices & Radiological Health, to Advanced Bionics
24 Corp. (Apr. 27, 2004) (approving PMA No. P030017),
25 [https://www.bostonscientific.com/content/dam/bostonscientific/Reimbursement/Neu-](https://www.bostonscientific.com/content/dam/bostonscientific/Reimbursement/Neuromodulation/Resources/Other%20Resources/FDA%20Approval%20Letter%20-%20Precision%20Spinal%20Cord%20Stimulation%20Syst.pdf)
26 [romodulation/Resources/Other%20Resources/FDA%20Approval%20Letter%20-](https://www.bostonscientific.com/content/dam/bostonscientific/Reimbursement/Neuromodulation/Resources/Other%20Resources/FDA%20Approval%20Letter%20-%20Precision%20Spinal%20Cord%20Stimulation%20Syst.pdf)
27 [%20Precision%20Spinal%20Cord%20Stimulation%20Syst.pdf](https://www.bostonscientific.com/content/dam/bostonscientific/Reimbursement/Neuromodulation/Resources/Other%20Resources/FDA%20Approval%20Letter%20-%20Precision%20Spinal%20Cord%20Stimulation%20Syst.pdf); *see also* FDA,
28 *Premarket Approval (PMA) Database: P030017*,
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P030017>.

effectiveness results. *Id.* The SSED lists "actual experience" as one source of safety information, *id.* § X.A, but the "CDRH Decision" section of the SSED, the decision of the FDA's Center for Devices and Radiological Health ("CDRH"), the FDA component responsible for premarket review of medical devices, does not mention it.

52. In its Decision, the CDRH made the substitution explicit: "The determination of the safety and effectiveness of the PRECISION™ System was based on available published clinical studies for similar implanted spinal cord stimulation systems." The agency concluded that "the PRECISION™ System is **sufficiently similar** to the SCS systems reported in literature in regard to intended use, targeted patient population, technology, device design, and electrical output characteristics," and stated that it had taken into consideration "the least burdensome means to market." SSED § XII (CDRH Decision) (emphasis added).

53. The CDRH Decision further states that the FDA "concluded that these available published clinical studies constitute valid scientific evidence for the purposes of determining safety and effectiveness," and that "this evidence, when combined with the nonclinical data included in the PMA," provided reasonable assurance of the safety and effectiveness of the Precision System. *Id.* The agency's recital of the statutory standard thus rested on (a) clinical literature concerning other manufacturers' devices and (b) nonclinical testing, not on any clinical investigation of the Precision System adequate to support the required determination.

54. The SSED does not state that the requirement of well-controlled investigations was "not reasonably applicable to the device," the circumstance in which 21 C.F.R. § 860.7(e)(2) permits the agency to authorize reliance on other valid scientific evidence of effectiveness.

55. Lead durability was an important aspect of the approval question already apparent in the record before FDA. The SSED's historical adverse-event table identified 540 lead-breakage or lead-failure events. SSED § X.D, tbl. 3. Its account of

Precision's own limited clinical experience reported lead migration requiring repositioning and subsequent replacement, as well as pain requiring lead explantation. *Id.* § X.E, tbl. 4. Those findings put the clinical consequences of lead performance directly before the agency.

56. FDA described flex, pull, and compatibility testing of Precision's leads and testing of component reliability. SSED §§ IX.C, IX.J. The critical question was whether the conditions and acceptance criteria of those tests, together with the clinical evidence, supported safe and effective performance of the implanted Precision system over time. Plaintiffs allege that FDA failed to explain how the testing and historical experience resolved that question for the particular system it approved.

57. The missing analysis was consequential. Electrical-output comparability does not establish mechanical durability at the lead-anchor interface. Clinical experience with another system supports the safety of Precision only through a scientifically justified connection to the design, implantation conditions, and failure risks of Precision itself. FDA's stated similarity rationale left that connection unexplained, despite the lead-failure evidence and the limited duration of Precision's reported human experience.

58. FDA approved P030017 three years after retaining Class III status for implanted SCS systems because of device-failure and design risks. Its reliance on literature concerning other systems and on nonclinical testing required a reasoned explanation of how that evidence resolved the clinical questions for Precision. The SSED's general similarity conclusion did not reconcile the approval with the specific concern identified in the 2001 decision: whether the device's design would deliver safe and effective therapy in patients. The SSED does not mention the 2001 denial. In substance, the FDA approved the device on a standard lower than that which would have applied if it had been reclassified into Class II, on the basis of literature

concerning other devices and bench and animal testing, the kind of showing it had found inadequate when it denied reclassification.

C. The Supplements Through Which the Devices Implanted in Plaintiffs Reached the Market

59. Since 2004, Boston Scientific has marketed successive generations of SCS devices, incorporating multiwaveform stimulation, posture-adaptive programming, expanded electrode arrays, and redesigned battery and lead architectures, under supplements to PMA P030017 rather than through any new Premarket Approval. The FDA's PMA database lists supplements to PMA P030017 numbered from S001 through S399, more than 370 of which the FDA has approved.¹²

60. **Supplement S100 (Linear leads).** On July 19, 2010, the FDA approved Supplement S100, received February 18, 2010, as a "Normal 180 Day Track" supplement.¹³ It introduced the Linear 3-4 and 3-6 spinal cord stimulation leads, with electrode contact spacings of 4 mm and 6 mm. Linear 3-4 leads were later the subject of the May 2020 Class II recall described below.

61. **Supplement S134 (Precision Spectra).** Boston Scientific submitted Supplement S134 on May 7, 2012, and on December 21, 2012, the FDA approved it as a "Normal 180 Day Track" supplement for a "Change Design/Components/Specifications/Material."¹⁴ It authorized the Precision Spectra System, including the Model SC-1132 Precision Spectra implantable pulse generator,

¹² See FDA, *Premarket Approval (PMA) Database: P030017*, <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P030017> (listing supplements).

¹³ FDA, *Premarket Approval (PMA) Database: P030017/S100*, <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P030017S100>.

¹⁴ FDA, *Premarket Approval (PMA) Database: P030017/S134*, <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P030017S134>.

1 which introduced a 32-contact architecture and expanded lead configurations enabling
2 multi-source current steering.

3 **62. Supplement S191 (Infinion CX leads).** On June 17, 2014, the FDA
4 approved Supplement S191 as a 180-day supplement.¹⁵ It introduced the Infinion CX
5 16-contact lead, which is now the subject of the Class I recall described in Section V.F.

6 **63. Supplement S152 (CoverEdge paddle lead).** On August 26, 2014, the
7 FDA approved Supplement S152 as a 180-day supplement for the CoverEdge 32-
8 contact surgical paddle lead.¹⁶

9 **64. Supplement S235 (Precision Montage and Precision Montage MRI).**
10 Boston Scientific submitted Supplement S235 on September 10, 2015, and on April
11 28, 2016, the FDA approved it as a "Normal 180 Day Track" supplement for a "Change
12 Design/Components/Specifications/Material." The approval order describes it as the
13 "addition of the Precision Montage MRI and Precision Montage System
14 Components."¹⁷

15 **65. Supplement S271 (Spectra WaveWriter).** Boston Scientific submitted
16 Supplement S271 on December 16, 2016, and on March 13, 2017, the FDA approved
17 it through the "Real-Time Process." The approval order authorized "firmware/software
18 updates" to the Precision Spectra implantable pulse generator, external trial stimulator,
19 remote control, and programming software, stating that "[t]he firmware/software has
20 been updated to support new features" and that the Precision Spectra System "will be

21
22 ¹⁵ FDA, *Premarket Approval (PMA) Database: P030017/S191*,
23 <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P030017S191>.

24 ¹⁶ FDA, *Premarket Approval (PMA) Database: P030017/S152*,
25 <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P030017S152>.

26 ¹⁷ FDA, *Premarket Approval (PMA) Database: P030017/S235*,
27 <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P030017S235>.
28

rebranded under the name Spectra WaveWriter SCS System."¹⁸ Those "new features" are the capabilities Boston Scientific then marketed as the first SCS platform able to deliver multiple stimulation waveforms simultaneously.

66. **Supplement S297 (subperception labeling).** On December 21, 2017, the FDA approved Supplement S297 as a 180-day supplement. It authorized labeling changes "associated with the demonstrated safety and effectiveness of subperception therapy."¹⁹

67. **Supplement S323 (Bluetooth activation).** On May 14, 2019, the FDA approved Supplement S323 through the Real-Time Process. It activated Bluetooth functionality in the Freelink RC4 remote control.²⁰

68. **Supplement S338 (WaveWriter Alpha).** Boston Scientific submitted Supplement S338 on April 23, 2020, and on December 1, 2020, the FDA approved it for "[t]he WaveWriter Alpha Spinal Cord Stimulator (SCS) System," as a "Normal 180 Day Track" supplement for a "Change Design/Components/Specifications/Material."²¹

¹⁸ FDA, *Premarket Approval (PMA) Database: P030017/S271*, <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P030017S271>.

¹⁹ FDA, *Premarket Approval (PMA) Database: P030017/S297*, <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P030017S297>.

²⁰ FDA, *Premarket Approval (PMA) Database: P030017/S323*, <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P030017S323>.

²¹ FDA, *Premarket Approval (PMA) Database: P030017/S338*, <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P030017S338>; *see also* Determination of Regulatory Review Period for Purposes of Patent Extension; WaveWriter Alpha Spinal Cord Stimulator System, Fed. Reg. Doc. No. 2024-24095 (Oct. 18, 2024) (stating that PMA P030017/S338 was submitted April 23, 2020 and approved December 1, 2020), <https://www.federalregister.gov/documents/2024/10/18/2024-24095/determination-of-regulatory-review-period-for-purposes-of-patent-extension-wavewriter-alpha-spinal>.

1 The WaveWriter Alpha introduced a redesigned implantable pulse generator and
2 battery system, with Bluetooth Low Energy wireless communication, in rechargeable
3 and non-rechargeable configurations.

4 69. **Supplement S358 (smartphone control).** On April 4, 2024, the FDA
5 approved Supplement S358 as a 180-day supplement. It authorized the mySCS GO
6 Therapy Controller App, a smartphone application that replaces the Freelink remote
7 control for controlling the WaveWriter Alpha implantable pulse generator.²²

8 70. **Supplement S371 (WaveWriter Alpha firmware).** On April 29, 2024,
9 the FDA approved Supplement S371 through the Real-Time Process. It changed the
10 WaveWriter Alpha pulse generator's firmware to delay time-clock synchronization
11 until charging is complete, together with a change to an internal capacitor.²³ Less than
12 three months later, Boston Scientific initiated Recall No. Z-2617-2024 for WaveWriter
13 Alpha pulse generators that may reset during charging.

14 71. **Supplement S392 (Celestia).** On May 21, 2026, the FDA approved
15 Supplement S392 through the Real-Time Process. It changed the management of
16 compliance voltage in the firmware of the WaveWriter Alpha pulse generator and
17 external trial stimulator, and the devices are now commercialized under a new brand
18 name, "Celestia."²⁴

19 72. Boston Scientific itself presents these devices as distinct products. It
20 currently markets the Precision Montage, Spectra WaveWriter, and WaveWriter Alpha

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22 ²² FDA, *Premarket Approval (PMA) Database: P030017/S358*,
23 <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P030017S358>.

24 ²³ FDA, *Premarket Approval (PMA) Database: P030017/S371*,
25 <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P030017S371>.

26 ²⁴ FDA, *Premarket Approval (PMA) Database: P030017/S392*,
27 <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P030017S392>.
28

as three separate systems, and in a January 11, 2018, press release it described the Spectra WaveWriter as "industry leading SCS technology."²⁵ Yet every one of these systems is marketed under the single original approval, PMA P030017.

D. The FDA Approved Fundamental Redesigns Through Lesser Supplement Pathways

73. Of the more than 370 supplements to PMA P030017 that the FDA has approved, only three, S275, S357, and S363, were reviewed as panel-track supplements, and each sought only to expand the devices' indications for use.²⁶ None of the design, component, firmware, or software changes described in Section V.C, including the new pulse generator platforms approved in S134, S235, and S338 and the Spectra WaveWriter platform approved in S271, was reviewed as a panel-track supplement. The FDA even approved labeling based on the "demonstrated safety and effectiveness of subperception therapy" through a 180-day supplement, S297, rather than a panel-track supplement.

74. By statute, a real-time supplement is limited to "a minor change to the device, such as a minor change to the design of the device, software, sterilization, or labeling," 21 U.S.C. § 379i(4)(D), and a 180-day supplement is one that "is not a panel-

²⁵ Press Release, Boston Scientific, *Boston Scientific Receives U.S. FDA Approval for Spectra WaveWriter™ Spinal Cord Stimulator System* (Jan. 11, 2018), <https://news.bostonscientific.com/2018-01-11-Boston-Scientific-Receives-U-S-FDA-Approval-for-Spectra-WaveWriter-TM-Spinal-Cord-Stimulator-System>.

²⁶ See FDA, *Boston Scientific Spinal Cord Stimulation System – P030017/S275*, <https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm588305.htm>; FDA, *Spectra WaveWriter, WaveWriter Alpha, WaveWriter Alpha Prime Spinal Cord Stimulation Systems – P030017/S363*, <https://www.fda.gov/medical-devices/recently-approved-devices/spectra-wavewriter-wavewriter-alpha-wavewriter-alpha-prime-spinal-cord-stimulation-systems>; FDA, *Spinal Cord Stimulator System Information for Patients*, PMA No. P030017/S357, https://www.accessdata.fda.gov/cdrh_docs/pdf3/P030017S357D.pdf.

1 track supplement" and requests a significant change, *id.* § 379i(4)(C). The FDA thus
2 treated firmware that transformed the Precision Spectra into a simultaneous multi-
3 waveform platform as a "minor change," and it approved a redesigned pulse generator,
4 battery, and wireless communication system without panel-track review. The FDA
5 used the same real-time process for Bluetooth activation in S323 and for WaveWriter
6 Alpha firmware changes affecting charging and compliance voltage in S371 and S392.

7 75. Those changes were cumulative and substantial. They include the addition
8 of simultaneous multiwaveform stimulation (tonic, burst, and sub-perception
9 programming); the redesign of the implantable pulse generator battery system and its
10 communication capabilities; the addition of Bluetooth-enabled communication and
11 smartphone-based patient control; the integration of posture-adaptive stimulation
12 algorithms; and the expansion of lead configurations and multi-source current delivery
13 systems. As a result, the devices implanted in Plaintiffs are fundamentally different
14 from the Precision System approved in 2004. Changes of that magnitude required a
15 new PMA or, at a minimum, a panel-track supplement supported by substantial clinical
16 data. 21 U.S.C. § 379i(4)(B).

17 76. Upon information and belief, in approving Supplements S100, S134,
18 S235, S271, and S338, the FDA did not require, and Boston Scientific did not submit,
19 clinical investigations demonstrating that the modified devices were safe and effective.

20 77. Additionally, the FDA could not have approved these supplements under
21 the statutory provision for incremental design changes. That provision directs approval
22 of a supplement for "an incremental change to the design of a device" when nonclinical
23 data show that the modification works as intended and "clinical data from the approved
24 application and any supplement to the approved application provide a reasonable
25 assurance of safety and effectiveness for the changed device." 21 U.S.C. §
26 360e(d)(5)(B)(i). That showing could not be made here. The approved application for
27 PMA P030017 contained no clinical data capable of providing that assurance, only
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1 literature regarding other manufacturers' devices and limited experience in 26
2 implanted subjects for which no effectiveness results were reported, and, upon
3 information and belief, no earlier supplement supplied it. Nor were the cumulative
4 changes that created the Precision Spectra, Precision Montage, Spectra WaveWriter,
5 and WaveWriter Alpha platforms "incremental." Upon information and belief, the
6 FDA did not require the additional clinical data that the statute authorizes when
7 necessary, *id.* § 360e(d)(5)(B)(ii), before approving Supplements S134, S235, S271,
8 and S338.

9 **E. The FDA Did Not Determine Whether Earlier Evidence Supported the**
10 **Changed Devices**

11 78. Each challenged supplement required FDA to evaluate the device in the
12 configuration that the supplement authorized. The common designation P030017 did
13 not establish that evidence supporting an earlier configuration demonstrated the safety
14 and effectiveness of a later system with materially different components,
15 programming, or therapeutic performance.

16 79. The earlier evidence's scientific applicability was essential to the approval
17 decision. FDA was required to determine whether that evidence addressed the changed
18 system's performance, conditions of use, and material risks, and whether additional
19 evidence was necessary to establish the required assurance of safety and effectiveness.

20 80. The challenged changes concerned the implanted systems' capacity to
21 deliver therapy. Their significance depended on the stimulation delivered, how the
22 components interacted in the approved configuration, and the clinical consequences of
23 those features. Calling a submission a software update, a component change, or an
24 addition to an existing product family did not answer those questions.

25 81. Plaintiffs allege that the prior evidence did not provide a scientifically
26 adequate foundation for supplemental approval. FDA nevertheless authorized those
27 devices through the challenged supplement orders without adequately explaining why
28

1 the evidence remained applicable or why neither a new PMA nor panel-track review
2 was required.

3 82. The cumulative changes were material to that inquiry. At each challenged
4 approval, FDA was required to assess the resulting configuration and the applicability
5 of the evidence on which it relied. Reliance on an intervening supplement required
6 consideration of what that supplement's evidence actually established about the system
7 then being approved.

8 83. These failures affected the substance of the approval decisions. They
9 authorized the changed systems without resolving the specific questions of therapeutic
10 performance and safety identified above. By adopting these allegations, the Plaintiffs
11 identify the relevant approved configuration, implanted components, and resulting
12 injuries in their incorporated individual allegations.

13 84. Because every one of these devices rests on the foundation of PMA
14 P030017, the defect in the 2004 approval runs through the entire product line, including
15 the devices implanted in Plaintiffs. That derivative defect is in addition to, and
16 independent of, the defects in each supplement approval alleged in this Section.

17 **F. Post-Market Experience**

18 85. The post-market record confirms the consequences of approving these
19 devices without a device-specific safety-and-effectiveness determination. On
20 September 3, 2020, the FDA advised health care providers that it had received 107,728
21 medical device reports concerning spinal cord stimulators in the four years beginning
22 July 27, 2016, and that the most frequently reported patient problem was inadequate
23 pain relief, reported 30,321 times. Among the device problems most frequently
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1 reported were impedance problems, reported 11,413 times, and migration, reported
2 7,727 times.²⁷

3 86. A 2023 Cochrane systematic review of randomized and cross-over trials
4 concluded that SCS for low back pain probably does not provide sustained clinical
5 benefits that would outweigh the costs and risks of the surgical intervention.²⁸

6 87. Publicly available adverse-event reports, published literature, and post-
7 market surveillance data also associate Boston Scientific's SCS systems with device
8 migration and loss of therapeutic coverage, lead fractures requiring surgical revision,
9 battery depletion and communication failures, stimulation-induced autonomic
10 dysfunction such as urinary incontinence and orthostatic hypotension, and persistent
11 ineffective pain relief despite extensive reprogramming.

12 88. Boston Scientific's SCS devices have been the subject of repeated recalls,
13 including the Infinion CX recall described below, as well as: (a) an August 2024 Class
14 II recall, still open, of 77,674 WaveWriter Alpha implantable pulse generator kits,
15 Models SC-1216 and SC-1232, which may reset during charging, causing a transient
16 loss of stimulation and undesired sensations that may lead patients to seek surgical
17 replacement or revision, a defect the FDA attributed to "software design" (Recall No.
18 Z-2617-2024); (b) a June 2026 Class II recall of the Klik X anchor (Recall No. Z-2404-
19 2026); (c) a May 2020 Class II recall of Linear 3-4 leads, the Artisan 2x8 surgical
20 paddle lead, lead extensions, and the Precision M8 adapter; and (d) earlier Class II
21

22 ²⁷ FDA, *Conduct a Trial Stimulation Period Before Implanting a Spinal Cord*
23 *Stimulator (SCS) - Letter to Health Care Providers* (Sept. 3, 2020) (archived Mar. 31,
24 2023), [https://web.archive.org/web/20230331003134/https://www.fda.gov/medical-](https://web.archive.org/web/20230331003134/https://www.fda.gov/medical-devices/letters-health-care-providers/conduct-trial-stimulation-period-implanting-spinal-cord-stimulator-scs-letter-health-care-providers)
25 [devices/letters-health-care-providers/conduct-trial-stimulation-period-implanting-](https://web.archive.org/web/20230331003134/https://www.fda.gov/medical-devices/letters-health-care-providers/conduct-trial-stimulation-period-implanting-spinal-cord-stimulator-scs-letter-health-care-providers)
26 [spinal-cord-stimulator-scs-letter-health-care-providers](https://web.archive.org/web/20230331003134/https://www.fda.gov/medical-devices/letters-health-care-providers/conduct-trial-stimulation-period-implanting-spinal-cord-stimulator-scs-letter-health-care-providers).

26 ²⁸ Adrian C. Traeger et al., *Spinal Cord Stimulation for Low Back Pain*, Cochrane
27 Database of Systematic Reviews, Issue 3, Art. No. CD014789 (2023),
28 <https://doi.org/10.1002/14651858.CD014789.pub2>.

recalls of Precision Linear leads (January 2007) and Precision implantable pulse generators (October 2007 and February 2008).²⁹

89. The Infinion CX recall gives concrete clinical significance to the lead-durability problem. According to the FDA, as of May 27, 2026, there were 1,081 serious injuries associated with the issue underlying the recall.³⁰ FDA's September 3, 2026 notice identifies affected lead kits SC-2317-50 and SC-2317-70. Boston Scientific initiated the removal of unused leads through a June 17, 2026 customer letter, and FDA classified the recall as Class I. The recall covers 1,079 lead kits, was posted in the FDA's recall database on August 5, 2026, and remains open; the FDA identified its cause as "device design." FDA, Spinal Cord Stimulator Recall: Boston Scientific Removes Infinion CX Lead (Sept. 3, 2026); Recall No. Z-2879-2026.

²⁹ See generally FDA, *Medical Device Recalls Database* (search for PMA No. P030017), https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?start_search=1&number=P030017; see also FDA, *Class 2 Device Recall WaveWriter Alpha 16 IPG Kit, WaveWriter Alpha 32 IPG Kit*, <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRes/res.cfm?id=209084>; Boston Scientific, *Urgent Medical Device Advisory* (July 2024), https://www.bostonscientific.com/content/dam/bostonscientific/quality/documents/Recent%20Product%20Advisories/2024July_SCS_EffectsResetsRechargeableSCSIPGs.pdf; FDA, *Class 2 Device Recall Boston Scientific Clik X Anchor*, <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=220250>; FDA, *Class 2 Device Recall Artisan*, <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRes/res.cfm?id=179769>; FDA, *Class 2 Device Recall Precision*, <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfres/res.cfm?id=179905>; FDA, *Class 2 Device Recall Advanced Bionics Precision Linear Leads*, <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRES/res.cfm?id=49022>.

³⁰ FDA, *Spinal Cord Stimulator Recall: Boston Scientific Removes Infinion CX Lead* (Sept. 3, 2026), <https://www.fda.gov/medical-devices/medical-device-recalls-and-early-alerts/spinal-cord-stimulator-recall-boston-scientific-removes-infinion-cx-lead>.

1 90. The reported failure mechanism is mechanical stress on the lead body at
2 the anchor site, producing high impedance or fracture. The resulting loss of adequate
3 stimulation can require further intervention, including lead explantation and
4 replacement. This is a failure of the implanted system's physical ability to deliver the
5 therapy for which approval was granted.

6 91. FDA's notice documents the substantial patient harm associated with this
7 failure mode and the potential need for additional surgery. *Id.*

8 92. FDA's later SSED for P030017/S357 identifies Supplement S191 as the
9 approval reference for Infinion CX leads. SSED for P030017/S363 § IX, at 8. The
10 AccessGUDID record for model SC-2317-50 likewise identifies P030017, Supplement
11 191.³¹ The recalled lead therefore presents a specific example of a component
12 authorized through the supplementation of the original Precision approval that has been
13 associated with serious injuries.

14 93. The physical integrity of the lead and its interaction with the anchor are
15 essential to sustained stimulation. Plaintiffs allege that approval of a changed lead
16 required a supported evaluation of those characteristics and the resulting risks in
17 clinical use. Reliance on the original PMA or on clinical experience with an earlier
18 lead could support the changed component only through a reasoned assessment of
19 whether that evidence answered the safety questions raised by the component
20 approved. Upon information and belief, the FDA did not require clinical data on the
21 Infinion CX lead itself before approving Supplement S191.

22 94. For Plaintiffs implanted with the affected leads, the fracture and
23 impedance problem bears directly on the ongoing device injuries and remedial needs
24

25 ³¹ FDA, *Summary of Safety and Effectiveness Data*, PMA No. P030017/S363,
26 https://www.accessdata.fda.gov/cdrh_docs/pdf3/P030017S363B.pdf; *see also*
27 *AccessGUDID, Infinion™ CX (Model SC-2317-70)*,
<https://accessgudid.nlm.nih.gov/devices/M365SC2317700>.

1 alleged in their individual allegations. The recall also supplies concrete postmarket
2 information relevant to the agency’s continuing responsibilities under 21 U.S.C. §
3 360e(e), as pleaded in Count IV.

4 **G. Plaintiffs' Experiences with the Devices**

5 95. The devices implanted in Plaintiffs span the successive generations of
6 systems described in Section V.C. They include Precision Spectra, Precision Montage
7 MRI, Spectra WaveWriter, and WaveWriter Alpha implantable pulse generators,
8 implanted between 2016 and 2022, each marketed under a supplement to PMA
9 P030017.³²

10 96. Some of those devices are subject to the recalls described in Section V.F.
11 At least one Plaintiff's replacement pulse generator is a WaveWriter Alpha, Model SC-
12 1216, a model covered by Recall No. Z-2617-2024.³³

13 97. None of these devices delivered the pain relief Plaintiffs were told to
14 expect. Instead, Plaintiffs report worsening pain, electric shocks and shocking
15 sensations, burning at the implant site, numbness, and loss of control of the
16 extremities.³⁴

17 98. Several Plaintiffs developed autonomic and visceral symptoms after
18 implantation, including urinary and bowel incontinence, urinary retention,
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22 ³² See, e.g., *Robinette* Compl. ¶ 62 (Precision Spectra, Model SC-1132, implanted
23 2016); *Bayhi* Compl. ¶ 63 (Spectra WaveWriter, Model SC-1160, implanted 2017);
24 *Lamy* Compl. ¶ 63 (Precision Montage MRI, Model SC-1200, implanted 2019);
25 *Albright* Compl. ¶¶ 63, 66 (Model SC-1200, implanted 2018 and replaced in 2022
with a WaveWriter Alpha, Model SC-1216).

26 ³³ See *Albright* Compl. ¶ 66.

27 ³⁴ See, e.g., *Albright* Compl. ¶¶ 64–65, 67; *Bayhi* Compl. ¶ 64; *Lamy* Compl. ¶¶ 64,
28 67; *Robinette* Compl. ¶¶ 63–65.

gastroparesis, and cardiac symptoms. In at least one case, chest pain and shortness of breath resolved when the stimulator was turned off.³⁵

99. Plaintiffs have also experienced the lead and device failures documented in the post-market record, including lead migration and fracture, revision surgery, and a malfunction that overstimulated one Plaintiff and required emergency hospitalization.³⁶

100. Boston Scientific representatives reprogrammed Plaintiffs' devices repeatedly, in at least one case fifteen or more times over five years, and told Plaintiffs that their experiences were uncommon and that reprogramming would deliver the promised relief. It did not. In at least one case, a Boston Scientific representative told a Plaintiff after implantation that the Plaintiff was not a candidate for the device because it was not made to address the Plaintiff's condition.³⁷

101. These experiences are consistent with the gap in the record on which the FDA relied. When the FDA approved the Precision System, no clinical investigation of that system had established that it would relieve pain, see Section V.B, and when the FDA approved the redesigned systems that followed, it did not require clinical investigations establishing that they would do so either, see Sections V.C–V.E.

102. The devices remain implanted in some patients. Some no longer hold a charge or accept reprogramming, and at least one cannot be charged because charging burns the skin. Yet the retained devices continue to cause pain, burning, unwanted shocks, and inflammation at the implant site.³⁸

³⁵ See, e.g., *Albright* Compl. ¶ 64; *Bayhi* Compl. ¶¶ 64, 66, 68; *Lamy* Compl. ¶ 64; *Robinette* Compl. ¶¶ 63, 66.

³⁶ See, e.g., *Robinette* Compl. ¶¶ 65–66; *Bayhi* Compl. ¶¶ 67–68.

³⁷ See, e.g., *Albright* Compl. ¶¶ 65, 67; *Bayhi* Compl. ¶ 65; *Lamy* Compl. ¶ 65; *Robinette* Compl. ¶ 64.

³⁸ See, e.g., *Albright* Compl. ¶ 68; *Bayhi* Compl. ¶ 70; *Lamy* Compl. ¶ 69; *Robinette* Compl. ¶ 69.

103. Plaintiffs whose devices remain implanted want them removed, and several have told their physicians so. In at least one case, treating providers documented years ago that replacement of the entire system was anticipated, but it has not occurred. Plaintiffs have not been able to undergo removal. Some have health insurance but cannot afford the co-payments and other out-of-pocket costs of the surgery, and at least one has been unable to find a physician willing to perform it.³⁹

VI. STANDING

104. Plaintiffs have standing to seek the declaratory and injunctive relief requested. Each Plaintiff has suffered a concrete and particularized injury that is actual and ongoing, that is fairly traceable to the challenged approvals, and that a favorable decision is likely to redress. Each Plaintiff has suffered at least one of the injuries described below.

105. **Injury in fact: ongoing physical injury.** As of the filing of this Consolidated APA Complaint, at least four Plaintiffs remain implanted with a Boston Scientific SCS device marketed under the challenged approvals. The device has not provided the promised pain relief, has caused and continues to cause additional injuries, and remains in the Plaintiff's body only because the Plaintiff cannot afford the surgery to remove it, whether for lack of insurance or because of co-payments and other out-of-pocket costs, or cannot find a physician to perform it. Plaintiffs have told their physicians, and in some cases Boston Scientific's representatives, that the device has failed, that it has injured them, and that they want it removed. See Section V.G. That injury is not past and completed. It is present and continuing, and it will persist unless and until the device is removed.

³⁹ See, e.g., *Albright* Compl. ¶¶ 69–70; *Bayhi* Compl. ¶ 71; *Lamy* Compl. ¶¶ 66, 70; *Robinette* Compl. ¶¶ 69–70.

1 106. Each such Plaintiff carries in their body a device that has not provided the
2 promised therapeutic benefit, continues to cause the injuries described in Section V.G,
3 and remains subject to the failure modes documented in the post-market record,
4 including lead fracture and migration, which may require further surgery. Those
5 present harms, together with the substantial risk of further harm for as long as the
6 device remains implanted, are concrete and imminent injuries.

7 107. **Standing exists at the outset of this action.** Each Plaintiff suffered the
8 ongoing physical injury described above when that Plaintiff first asserted an APA
9 claim against the FDA, and continues to suffer it. Any Plaintiff who later adopts this
10 Consolidated APA Complaint will allege, in that Plaintiff's short-form or individual
11 complaint, the facts establishing that Plaintiff's standing as of the date of adoption.

12 108. **Injury in fact: the preemption bar.** Each Plaintiff against whom Boston
13 Scientific has asserted federal preemption under 21 U.S.C. § 360k(a) suffers an
14 additional, present injury to that Plaintiff's legally protected interest in pursuing state-
15 law remedies. Boston Scientific contends that, because the device carries a PMA,
16 preemption bars that Plaintiff's state-law claims for the injuries the device caused. But
17 for the challenged approval, that defense would not exist.

18 109. **Traceability.** Plaintiffs' injuries are fairly traceable to the FDA's
19 approvals. Each Plaintiff's ongoing physical injury flows from a device that could not
20 lawfully have been marketed, sold, or implanted without the challenged approvals. Any
21 preemption defense asserted against a Plaintiff exists only because the FDA granted
22 and maintains PMA P030017.

23 110. **Traceability also runs to each challenged supplement.** Each Plaintiff's
24 device was marketed under PMA P030017 and one or more of its supplements, and
25 each supplement under which the device was marketed was approved before that
26 Plaintiff's device was implanted. Upon information and belief, implanted devices have
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1 since received firmware changes approved through later supplements, including S371
2 and S392.

3 111. **No speculative causal chain.** Plaintiffs' injuries do not depend on a
4 speculative chain of independent decisions by third parties not before the Court. *Cf.*
5 *Murthy v. Missouri*, 603 U.S. 43, 57–58 (2024). The challenged approval orders are
6 the legal authorization under which each Plaintiff's device was marketed and
7 implanted, and the regulatory predicate on which Boston Scientific's preemption
8 defense rests. Each Plaintiff's injuries, and the connection between those injuries and
9 the challenged orders, are alleged with particularity in Section V.G and in each
10 Plaintiff's individual complaint. *See Global Nurse Force v. Trump*, No. 25-cv-08454-
11 HSG, slip op. at 12–13 (N.D. Cal. Sept. 30, 2026) (rejecting *Murthy*-based challenge
12 to standing where plaintiffs offered concrete, plaintiff-specific facts linking the
13 challenged agency policies to their injuries).⁴⁰ Further, Boston Scientific's assertion of
14 a preemption defense is not speculative. Boston Scientific has already asserted that
15 defense in motions to dismiss previously filed in individual cases that were transferred
16 to or made part of this MDL, and has repeatedly stated that it intends to assert that
17 defense in the upcoming motions to dismiss the Master Personal Injury Complaint, and
18 any such defense would apply to the Plaintiffs whose claims against the FDA are
19 asserted herein.

20 112. **Redressability.** A favorable decision will redress Plaintiffs' injuries.
21 Plaintiffs seek a declaration that PMA P030017 and the challenged supplements were
22 approved unlawfully, vacatur of those approvals, and remand to the FDA for
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25 ⁴⁰ Order Granting in Part and Denying in Part Plaintiffs' Motion for a Preliminary
26 Injunction, *Global Nurse Force v. Trump*, No. 4:25-cv-08454-HSG (N.D. Cal. Sept.
27 30, 2026); *see* Docket, *Global Nurse Force v. Trump*, No. 4:25-cv-08454 (N.D. Cal.),
28 <https://www.courtlistener.com/docket/71541425/global-nurse-force-v-trump/>.

1 reconsideration under the correct statutory standard, together with the further relief
2 described below. 5 U.S.C. § 706(2).

3 113. On remand, the FDA has statutory tools that would directly redress
4 Plaintiffs' ongoing injuries. It may withdraw or temporarily suspend approval. 21
5 U.S.C. § 360e(e). If it determines that the devices present "an unreasonable risk of
6 substantial harm to the public health," it may order notification of the health
7 professionals who use the devices and of the patients in whom they are implanted. *Id.*
8 § 360h(a). If it further finds reasonable grounds to believe the devices were not
9 properly designed or manufactured, it may order the manufacturer to submit a plan to
10 repair or replace the devices or refund their purchase price at no cost to patients, who
11 must be reimbursed for the "reasonable and foreseeable expenses actually incurred" in
12 obtaining the remedy. *Id.* § 360h(b). Those expenses could include the cost of the
13 removal surgery that Plaintiffs cannot now afford. *Id.* § 360h(b)(2)–(3).

14 114. Vacatur would also redress the preemption injury of any Plaintiff against
15 whom Boston Scientific has asserted or will assert preemption. Setting aside PMA
16 P030017 would remove the legal predicate (a valid, in-force Premarket Approval) on
17 which that defense depends.

18 115. **Vacatur of the supplement approvals.** Vacatur of the unlawful
19 supplement approvals would leave the modified devices without a valid premarket
20 approval, 21 U.S.C. § 351(f)(1)(B), requiring the FDA to address their status through
21 its notification, repair, replacement, refund, and recall authorities. 21 U.S.C. § 360h;
22 21 C.F.R. pt. 810. And because the FDA continues to approve, through real-time and
23 other lesser supplements, firmware and software changes installed in devices already
24 implanted, relief requiring lawful review of those changes would directly affect what
25 may be done to the devices still currently in Plaintiffs' bodies.

26 116. **Procedural injury.** Plaintiffs were also deprived of the procedural
27 protections Congress required for significant changes to a Class III device, including
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1 panel-track review supported by new clinical data. Because Plaintiffs have a concrete
2 interest in the safety of devices that remain implanted in their bodies, they need not
3 show that the FDA's decision on remand would necessarily differ. *See Lujan v.*
4 *Defenders of Wildlife*, 504 U.S. 555, 572 n.7 (1992).

5 117. **Vacatur and the scope of relief.** Vacatur under 5 U.S.C. § 706(2)
6 operates on the unlawful agency action itself. It does not implicate the concerns about
7 universal injunctions addressed in *Trump v. CASA, Inc.*, 606 U.S. 831 (2025). *See*
8 *Natural Grocers v. Rollins*, 157 F.4th 1143, 1170 n.7 (9th Cir. 2025);⁴¹ *Global Nurse*
9 *Force*, slip op. at 32–33 (vacating agency policies notwithstanding the government's
10 argument that relief must be limited to the moving plaintiffs). To the extent Plaintiffs
11 seek injunctive relief, they seek only the relief necessary to provide complete relief to
12 each Plaintiff. The public interest is served by the agency's compliance with the APA.
13 *California v. Azar*, 911 F.3d 558, 581 (9th Cir. 2018); *Global Nurse Force*, slip op. at
14 31–32.

15 118. An actual controversy exists between Plaintiffs and Defendants within the
16 meaning of 28 U.S.C. § 2201(a). The FDA and Boston Scientific contest Plaintiffs'
17 APA claims: Boston Scientific and the FDA have moved to dismiss the APA claims in
18 some member actions, and the FDA has stated that it will move to dismiss them going
19 forward. *See* Joint Submission Regarding APA Claims Against the U.S. Food and Drug
20 Administration at 1-2, 7, ECF No. 64 (Sept. 4, 2026). No court adjudicating a state-
21 law claim against Boston Scientific can simply set aside an FDA approval (although it
22 can adjudicate the validity of Boston Scientific's actions with regard to the approval
23 process); only an action against the agency under the APA can provide that relief.

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26 ⁴¹ *Natural Grocers v. Rollins*, No. 22-16770 (9th Cir. Oct. 31, 2025),
27 <https://cdn.ca9.uscourts.gov/datastore/opinions/2025/10/31/22-16770.pdf>.
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VII. REVIEWABILITY, EXHAUSTION, AND TIMELINESS

119. **Final agency action.** The FDA's grant of PMA P030017 and its orders approving the challenged supplements are final agency actions subject to review under 5 U.S.C. § 704. Each marked the consummation of the agency's decision-making process and determined rights and obligations by authorizing the marketing of the devices and conferring the regulatory status from which legal consequences flow, including the preemption defense that Boston Scientific has asserted in member actions under 21 U.S.C. § 360k(a). *Bennett v. Spear*, 520 U.S. 154, 177-78 (1997).

120. **No other adequate remedy.** No statute affords Plaintiffs an adequate alternative avenue of review. The MDA's special-review provision, 21 U.S.C. § 360g(a), authorizes petitions to a court of appeals within thirty days of certain enumerated device regulations and orders. As to premarket approval, it reaches only orders issued after the administrative review procedure of 21 U.S.C. § 360e(g), *id.* § 360g(a)(4); it does not provide for review of an order approving a PMA application under § 360e(d). Additionally, Congress provided that the remedies in § 360g "shall be in addition to and not in lieu of any other remedies provided by law." *Id.* § 360g(e). In any event, that route required a request for administrative review under § 360e(g) within thirty days after the FDA posted its summary of the 2004 approval, *see* Approval Order at 2, long before any Plaintiff had been implanted or injured.

121. **The claims are reviewable and are not committed to agency discretion.** Counts I and II challenge the FDA's affirmative, discrete decisions to grant a Premarket Approval and its supplements, not any decision to refrain from enforcement. Counts III and IV, pleaded in the alternative, rest on duties the statute states in mandatory terms. 21 U.S.C. § 360e(d)(2), (e)(1), (e)(3). Courts apply a "strong presumption favoring judicial review of administrative action." *Pacito v. Trump*, 169

1 F.4th 895, 930 (9th Cir. 2026)⁴² (quoting *Weyerhaeuser Co. v. U.S. Fish & Wildlife*
2 *Serv.*, 586 U.S. 9, 23 (2018)); *see Global Nurse Force*, slip op. at 25.

3 122. **No exhaustion is required.** No statute or FDA rule, including 21 C.F.R.
4 § 10.45(b), renders the challenged approvals inoperative pending a citizen petition or
5 other administrative review. The 2004 approval took effect immediately ("You may
6 begin commercial distribution of the device upon receipt of this letter"), and the
7 optional administrative review the FDA offered ("any interested person may seek
8 review") did not suspend it. Approval Order at 1-2. Plaintiffs therefore were not
9 required to exhaust administrative remedies before seeking judicial review. *See Darby*
10 *v. Cisneros*, 509 U.S. 137, 154 (1993). Nor is a request for discretionary agency relief
11 a prerequisite to standing or to review, and the agency's failure to act on such a request
12 would not render Plaintiffs' injuries speculative. *See Global Nurse Force*, slip op. at
13 12, 15 (declining to require plaintiffs to seek a discretionary exception before suing,
14 and holding that "Defendants' indefinite delay does not make Plaintiffs' harm
15 speculative").

16 123. **Any exhaustion requirement is excused as futile.** In the alternative, a
17 citizen petition asking the FDA to undo its own longstanding approval would serve no
18 purpose. The FDA has maintained the challenged approval for more than two decades,
19 has approved hundreds of supplements to it without requiring a new Premarket
20 Approval, and has not withdrawn, suspended, or reconsidered that approval in light of
21 the post-market record described in Section V.F.

22 124. **The claims are timely.** A claim under the APA accrues, and the six-year
23 limitations period of 28 U.S.C. § 2401(a) begins to run, when the plaintiff is injured by
24 final agency action, not when the agency acts. *Corner Post, Inc. v. Bd. of Governors of*
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26 ⁴² *Pacito v. Trump*, No. 25-1313 (9th Cir. Mar. 5, 2026),
27 <https://clearinghouse.net/doc/168917/>.

the Fed. Rsrv. Sys., 603 U.S. 799, 825 (2024). Plaintiffs were not injured by the 2004 approval until, at the earliest, they were implanted with a device marketed under PMA P030017. Plaintiffs' physical injuries are continuing, and several challenged supplement approvals, including S338, S371, and S392, issued within six years before Plaintiffs asserted their APA claims. The preemption injury did not accrue until Boston Scientific asserted preemption against a Plaintiff's state-law claims. Counts III and IV challenge the FDA's continuing failure to act. *See* Joint Submission Regarding APA Claims Against the U.S. Food and Drug Administration at 1-2, 7, ECF No. 64 (Sept. 4, 2026).

125. **Administrative record.** Review under 5 U.S.C. § 706 proceeds on "the whole record." Plaintiffs will request that the FDA lodge the complete certified administrative record for PMA P030017, including the original application, the SSED, the CDRH decision memoranda, any advisory-panel materials, and the record for each supplement approval challenged herein, together with the record of the FDA's 2001 denial of reclassification in Docket No. 00P-0788, on which Count I relies. Plaintiffs reserve the right to seek supplementation of the record and extra-record discovery where permitted, including on standing and to the extent the record is incomplete and reserve their right to amend this Complaint pending such completion of the record and any extra-record discovery.

VIII. CAUSES OF ACTION

COUNT I: Administrative Procedure Act, 5 U.S.C. § 706(2)(A), (C), (D)
Unlawful Grant of PMA P030017: Substitution of a Similarity Finding for the
Statutory Safety-and-Effectiveness Determination; Failure to Provide a Reasoned
Explanation and to Consider Important Aspects of Safety and Effectiveness

126. Plaintiffs reallege and incorporate all preceding paragraphs 1-125 as though fully set forth herein.

1 127. FDA's April 27, 2004 order approving PMA P030017 consummated its
2 review and authorized marketing of the Precision System. That order is final agency
3 action reviewable under 5 U.S.C. §§ 702, 704, and 706. The affected Plaintiffs'
4 devices, injuries, and requested relief are connected to that order as alleged above and
5 in their incorporated individual allegations.

6 128. The MDA required a supported determination of reasonable assurance of
7 the safety and effectiveness of Precision under its labeled conditions of use. 21 U.S.C.
8 §§ 360e(d)(1)–(2), 360c(a)(2)–(3); 21 C.F.R. § 860.7. FDA's recitation of that standard
9 did not satisfy its obligation to explain how the evidence supported the device-specific
10 determination.

11 129. **Statutory error.** The FDA did not lawfully make the required
12 determination for the Precision System. By its own account, it based approval on
13 published literature concerning other "similar" SCS systems, combined with
14 nonclinical data, and found the Precision System "sufficiently similar" to those devices.
15 SSED § XII. In doing so, the FDA substituted a comparative similarity inquiry, a
16 standard lower than the 510(k) substantial-equivalence pathway, for the device-
17 specific safety-and-effectiveness finding that the statute commands for a Class III
18 device requiring Premarket Approval.

19 130. Whether the MDA permits the FDA to grant Premarket Approval on that
20 basis is a question of statutory interpretation that this Court decides in the exercise of
21 its independent judgment, without deference to the agency. *Loper Bright*, 603 U.S. at
22 412-13. The statute does not permit it. The required assurance runs to "such device,"
23 21 U.S.C. § 360e(d)(2), and effectiveness must be shown by well-controlled
24 investigations, or by other valid scientific evidence sufficient for qualified experts to
25 conclude that the device under review will have its represented effect, *id.* §
26 360c(a)(3)(A)-(B). An approval resting on a finding of similarity in lieu of that
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1 showing is in excess of the FDA's statutory authority and not in accordance with law.
2 5 U.S.C. § 706(2)(A), (C).

3 **131. Failure to observe required procedure.** The FDA's regulations require
4 that valid scientific evidence of effectiveness "consist principally of well-controlled
5 investigations" unless the agency authorizes reliance on other valid scientific evidence,
6 a determination the agency may make where the requirement of well-controlled
7 investigations is "not reasonably applicable to the device." 21 C.F.R. § 860.7(e)(2).
8 The SSED makes no such determination. *See* Section V.B. The FDA's reliance on
9 literature concerning other devices without that determination was without observance
10 of procedure required by law. 5 U.S.C. § 706(2)(D).

11 **132. Failure of reasoned decision-making.** Independently of the statutory
12 error alleged above, and even if the MDA permitted the FDA to rely on evidence
13 concerning other devices as part of the basis for approving the Precision System, the
14 approval cannot stand because the FDA did not reasonably explain how that evidence
15 established the required assurance for this device.

16 **133.** Under *Motor Vehicle Manufacturers Association v. State Farm Mutual*
17 *Automobile Insurance Co.*, 463 U.S. 29, 43 (1983), FDA was required to examine the
18 relevant evidence and explain the connection between its factual findings and its
19 approval decision. Failure to address an important aspect of the approval question, or
20 reliance on reasoning inconsistent with the evidence before the agency, renders the
21 decision arbitrary and capricious under 5 U.S.C. § 706(2)(A).

22 **134.** FDA relied on clinical literature concerning other SCS systems, together
23 with nonclinical testing, to approve Precision. Its account of Precision's limited human
24 experience supplied no effectiveness outcomes. The resulting inference required an
25 explanation of why the source evidence established the safety and effectiveness of
26 Precision's design and approved uses. FDA's general assertion of similarity failed to
27 supply that explanation.
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1 135. The contemporaneous record identified lead failure as a material clinical
2 problem. FDA nevertheless failed to explain how its reliance on other systems’
3 experience and Precision’s preclinical test results established adequate durability and
4 sustained therapeutic performance under the conditions of implantation. The reported
5 human experience with Precision was too limited to resolve that unanswered question.
6 By approving Precision without a reasoned resolution of that issue, FDA failed to
7 consider an important aspect of the problem before it.

8 136. On this independent ground, the defect lies in the sufficiency of the
9 agency’s analysis: the evidence had to support the particular device, its conditions of
10 use, and its material risks. FDA’s stated reasoning left the inference from electrical and
11 technical comparability to clinical safety and effectiveness unsupported. That omission
12 affected both the assessment of expected benefit and the balancing of benefit against
13 device-failure risk.

14 137. FDA also failed to reconcile its approval rationale with its 2001
15 determination that device failure and improper design presented serious risks for
16 implantable SCS systems and required adequate clinical evaluation. 66 Fed. Reg.
17 21,401, 21,402 (Apr. 30, 2001). The agency was required to address that material
18 concern and explain a departure from an applicable prior judgment. *State Farm*, 463
19 U.S. at 43; *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515–16 (2009). The
20 similarity rationale did not explain how the clinical evidence and testing overcame the
21 identified design-risk problem for Precision. The SSED neither acknowledges the 2001
22 determination nor explains why literature concerning other devices, combined with
23 bench and animal testing, could supply the assurance that the FDA had found bench
24 and animal testing could not.

25 138. The FDA also failed to consider reasonable alternatives to approving the
26 Precision System on the record before it, including requiring a clinical investigation of
27 the Precision System itself, conditioning approval on post approval studies of lead
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1 durability and effectiveness, *see* 21 C.F.R. § 814.82(a)(2), or limiting the approved
2 conditions of use. Reasoned decision-making required the agency to consider such
3 alternatives and to explain why it rejected them. *Nebraska v. Su*, 121 F.4th 1, 17 (9th
4 Cir. 2024); *see Global Nurse Force*, slip op. at 26–27.

5 139. The 2004 approval was therefore (a) arbitrary, capricious, an abuse of
6 discretion, and otherwise not in accordance with law, 5 U.S.C. § 706(2)(A); (b) in
7 excess of the FDA's statutory authority and short of statutory right, and beyond the
8 statutory conditions for approval, *id.* § 706(2)(C); and (c) without observance of
9 procedure required by law, including the determination 21 C.F.R. § 860.7(e)(2)
10 requires before the agency may rely on evidence other than well-controlled
11 investigations, *id.* § 706(2)(D). Each ground alleged in this Count independently
12 warrants setting the approval aside. The failure was prejudicial because it permitted
13 approval without resolving deficiencies material to the required safety-and-
14 effectiveness finding. Under Ninth Circuit law, such an error is harmless only where
15 the agency's mistake "clearly had no bearing on the procedure used or the substance of
16 decision reached." *Azar*, 911 F.3d at 580 (internal quotations omitted); *see Global*
17 *Nurse Force*, slip op. at 31. That standard cannot be met here.

18 140. Plaintiffs request a declaration that the April 27, 2004 approval was
19 unlawful when issued, vacatur of that order, and remand for a lawful, reasoned, device-
20 specific determination under the governing PMA requirements, with relief addressing
21 the individual injuries alleged herein. 5 U.S.C. § 706(2).
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1 **COUNT II: Administrative Procedure Act, 5 U.S.C. § 706(2)(A), (C), (D)**
2 ***Unlawful Approval of Supplements to PMA P030017: Derivative Invalidity,***
3 ***Unlawful Review Pathway, and Failure to Establish Safety and Effectiveness of the***
4 ***Changed Devices***

5 141. Plaintiffs incorporate the preceding allegations and the individual
6 allegations identifying each adopting Plaintiff's device, challenged approval order,
7 injuries, and requested relief.

8 142. Each FDA order approving a supplement to PMA P030017 that
9 authorized the marketing of a device or component implanted in a Plaintiff is a discrete
10 final agency action reviewable under 5 U.S.C. §§ 702, 704, and 706. Those orders
11 include Supplement S100 (Linear leads, approved July 19, 2010), Supplement S134
12 (Precision Spectra, approved December 21, 2012), Supplement S191 (Infinion CX
13 leads, approved June 17, 2014), Supplement S235 (Precision Montage and Precision
14 Montage MRI, approved April 28, 2016), Supplement S271 (Spectra WaveWriter,
15 approved March 13, 2017), Supplement S338 (WaveWriter Alpha, approved
16 December 1, 2020), and Supplements S371 and S392 (WaveWriter Alpha firmware
17 changes, approved April 29, 2024 and May 21, 2026), together with any other
18 supplement under which a device or component implanted in a Plaintiff, including any
19 lead, extension, or anchor, was marketed, as identified in each Plaintiff's individual
20 complaint.

21 143. This Count challenges those orders on two independent grounds. First,
22 each order is derivatively unlawful because it rests on the 2004 approval challenged in
23 Count I. Second, and independently of Count I, each order was unlawful on its own
24 terms, so that this Count states a claim even if the 2004 approval were sustained. Each
25 challenged order completed FDA's review and authorized the marketing of a specified
26 changed device or component.
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1 144. **Derivative invalidity.** Each supplement approval rested on the original
2 2004 approval, which itself lacked a lawful, device-specific basis for the reasons
3 alleged in Count I. An approval that measures a modified device against an original
4 device never lawfully shown to be safe and effective cannot supply the reasonable
5 assurance the statute requires. If the Court sets aside the 2004 approval, each
6 challenged supplement approval should be set aside for that reason alone.

7 145. **Independent invalidity.** A PMA supplement is "evaluated under largely
8 the same criteria as an initial application," *Riegel*, 552 U.S. at 319, and a supplement
9 requesting a significant change in the design or performance of a device for which
10 substantial clinical data are necessary is a "panel-track supplement." 21 U.S.C. §
11 379i(4)(B); 21 C.F.R. § 814.39. Plaintiffs challenge the specific supplement approvals
12 identified above, not the supplement process itself.

13 146. FDA was required to apply the governing PMA requirements to the device
14 actually authorized by each order. Its approval determination depended on a supported
15 assessment of the changed configuration and the evidence necessary to establish its
16 safety and effectiveness.

17 147. As alleged above, the modifications identified as requiring new PMA
18 review introduced material changes for which the earlier preclinical and clinical
19 evidence was insufficient. FDA approved those devices as supplements without
20 adequately explaining why neither a new PMA nor panel-track review was required,
21 how the earlier evidence supported the changed devices, or how the unresolved clinical
22 questions had been answered.

23 148. Through the challenged supplements, the FDA approved cumulative
24 changes that transformed the Precision System, including simultaneous
25 multiwaveform stimulation, redesigned battery architecture and communication
26 capabilities, posture-adaptive stimulation algorithms, and expanded lead
27 configurations and multi-source current delivery. Those were significant changes in
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1 design or performance for which substantial clinical data were necessary, and the
2 statute therefore required, at a minimum, panel-track review. 21 U.S.C. § 379i(4)(B).
3 Upon information and belief, the FDA approved them without requiring clinical
4 investigations demonstrating that the modified devices were safe and effective, and
5 without panel-track review. Nor could the approvals rest on the incremental-change
6 provision, 21 U.S.C. § 360e(d)(5)(B), because the approved application contained no
7 clinical data capable of providing reasonable assurance of safety and effectiveness for
8 the changed devices, the cumulative changes were not incremental, and the FDA did
9 not require the additional clinical data that provision authorizes when necessary.
10 Processing these supplements outside the panel track was contrary to the statute and
11 without observance of procedure required by law. 5 U.S.C. § 706(2)(A), (C), (D).

12 149. In the alternative, even if the statute left the FDA discretion to process
13 some or all of these changes outside the panel track, FDA failed to select and justify
14 an appropriate supplement pathway. For S271, S371, and S392, the agency's use of the
15 real-time process required a supported determination that the authorized changes were
16 minor. For the challenged 180-day approvals, the agency was required to address
17 whether the changes necessitated substantial clinical evidence and the corresponding
18 review pathway. FDA's decisions failed to address the material performance changes
19 and evidentiary deficiencies alleged above.

20 150. Independently of the submission category, FDA failed to establish the
21 required assurance of safety and effectiveness for the changed devices. The agency
22 relied on supposed evidence from earlier devices without adequately explaining how
23 such evidence, if any, applied to the material changes identified in this Complaint.

24 151. These omissions constituted failures to consider important aspects of the
25 approval decisions and to articulate a rational connection between the evidence and the
26 approvals granted. They also left unexplained the agency's departure from its
27 articulated approach to materially changed devices. The challenged orders were
28

1 therefore arbitrary, capricious, and otherwise not in accordance with law under 5
2 U.S.C. § 706(2)(A). The FDA likewise failed to consider available alternatives to
3 approval by supplement, including requiring a new PMA, panel-track review, or the
4 additional clinical data the statute authorizes, 21 U.S.C. § 360e(d)(5)(B)(ii). *See Su*,
5 121 F.4th at 17.

6 152. Approval without the substantive showing required by the governing
7 PMA provisions also exceeded the statutory conditions of approval under 5 U.S.C. §
8 706(2)(C). Plaintiffs further seek relief under § 706(2)(D) for the specific failures to
9 observe binding approval procedures identified in this Complaint, including panel-
10 track review of significant design changes for which substantial clinical data were
11 necessary, 21 U.S.C. § 379i(4)(B).

12 153. The errors were prejudicial because they affected the evidence required
13 and the assessment of the changed devices' therapeutic performance and risks. Those
14 unresolved matters concern the devices and injuries identified in the adopting
15 Plaintiffs' individual allegations. *See Azar*, 911 F.3d at 580.

16 154. Plaintiffs request a declaration that the identified supplement approvals
17 were unlawful, vacatur of those orders, and remand for FDA to determine the proper
18 submission and review pathway and to apply the governing safety-and-effectiveness
19 requirements to the changed devices, including, if the 2004 approval is set aside, in
20 light of the FDA's redetermination of the original application.

21 **COUNT III: Administrative Procedure Act, 5 U.S.C. § 706(1)**
22 ***Agency Action Unlawfully Withheld***

23 155. Plaintiffs reallege and incorporate all preceding paragraphs 1-125 as
24 though fully set forth herein.

25 156. In the alternative, the FDA has unlawfully withheld a discrete agency
26 action that the statute requires: a lawful, device-specific determination under 21 U.S.C.

§ 360e(d) of whether there is a reasonable assurance that the Precision System and the devices marketed under its supplements are safe and effective. 5 U.S.C. § 706(1).

157. Plaintiffs seek an order compelling the FDA to undertake the device-specific safety-and-effectiveness review that 21 U.S.C. § 360e(d) requires.

COUNT IV: Administrative Procedure Act, 5 U.S.C. §§ 706(1), 706(2)(A)
Failure to Withdraw or Suspend Approval Under 21 U.S.C. § 360e(e)

158. Plaintiffs reallege and incorporate all preceding paragraphs 1-125 as though fully set forth herein.

159. Congress directed that the Secretary shall, after due notice and opportunity for an informal hearing, issue an order withdrawing approval of a PMA if, among other things, the Secretary finds, "on the basis of new information" evaluated "together with the evidence available to him when the application was approved, that there is a lack of a showing of reasonable assurance that the device is safe or effective under the conditions of use prescribed, recommended, or suggested in the labeling thereof." 21 U.S.C. § 360e(e)(1)(B). Where, after an opportunity for an informal hearing, the Secretary "determines there is reasonable probability that the continuation of distribution of a device under an approved application would cause serious, adverse health consequences or death," the Secretary "shall by order temporarily suspend the approval" and "shall proceed expeditiously . . . to withdraw" it. *Id.* § 360e(e)(3).

160. The new information available to the FDA since 2004 is extensive. It includes more than 107,000 adverse-event reports regarding SCS devices in a single four-year period, 30,321 of them reporting inadequate pain relief; Boston Scientific's report of 1,081 serious injuries associated with the Infinion CX lead, and the FDA's classification of that lead's recall as Class I with a root cause of "Device Design," reflecting the device-failure risk that the FDA identified in 2001 as "[t]he most serious risk to health presented by the device," 66 Fed. Reg. at 21,402; repeated recalls of Boston Scientific SCS components; and the 2023 Cochrane systematic review.

1 Evaluated together with the evidence available in 2004, which included no clinical
2 investigation of the Precision System adequate to support approval, that information
3 establishes a lack of a showing of reasonable assurance that the devices are safe and
4 effective.

5 161. The FDA has neither withdrawn nor suspended approval of PMA
6 P030017 or the challenged supplements, and has not made the determinations that §
7 360e(e) and 21 C.F.R. § 814.46 require. To the extent the record compels the findings
8 that trigger the statutory duty, the FDA's failure to act is agency action unlawfully
9 withheld or unreasonably delayed, 5 U.S.C. § 706(1), and its continued maintenance
10 of the approvals in the face of that record is arbitrary, capricious, and not in accordance
11 with law, *id.* § 706(2)(A).

12 162. Plaintiffs seek an order compelling the FDA to determine, within a
13 reasonable time set by the Court, whether the statutory criteria for withdrawal or
14 temporary suspension under 21 U.S.C. § 360e(e) are met as to PMA P030017 and the
15 challenged supplements, and to act in accordance with that determination.

16 IX. PRAYER FOR RELIEF

17 WHEREFORE, Plaintiffs respectfully request that the Court:

18 A. Declare, pursuant to 5 U.S.C. § 706(2) and 28 U.S.C. §§ 2201-2202, that the
19 FDA's grant of PMA P030017 was arbitrary, capricious, an abuse of
20 discretion, in excess of statutory authority, without observance of procedure
21 required by law, and otherwise not in accordance with law;

22 B. Declare that the FDA's orders approving Supplements S100, S134, S191,
23 S235, S271, S338, S371, and S392 (and any other supplement under which a
24 Plaintiff's device or component was marketed) were arbitrary, capricious, an
25 abuse of discretion, in excess of statutory authority, without observance of
26 procedure required by law, and otherwise not in accordance with law;

- 1 C. Hold unlawful, set aside, and vacate the FDA's approval of PMA P030017
2 under 5 U.S.C. § 706(2), and remand to the FDA;
- 3 D. Hold unlawful, set aside, and vacate the FDA's orders approving the
4 supplements to PMA P030017 under which the devices implanted in
5 Plaintiffs were marketed, under 5 U.S.C. § 706(2), and remand to the FDA;
- 6 E. In the alternative to vacatur, remand the challenged approvals to the FDA
7 without vacatur, with instructions to complete the required determinations
8 within a reasonable time set by the Court;
- 9 F. On remand, order the FDA to reconsider the devices under the correct
10 statutory standard within a reasonable time set by the Court, including
11 whether to withdraw or temporarily suspend approval under 21 U.S.C. §
12 360e(e), and whether to require notification, repair, replacement, or refund,
13 including reimbursement of the reasonable and foreseeable expenses
14 Plaintiffs incur in obtaining that remedy, under 21 U.S.C. § 360h;
- 15 G. Enjoin Defendants, and all persons acting under their direction, from giving
16 effect to the vacated approvals as to the devices implanted in Plaintiffs until
17 the FDA has completed a lawful, device-specific review under 21 U.S.C. §
18 360e(d);
- 19 H. Pending final judgment, issue all necessary and appropriate process to
20 postpone the effective date of, or to preserve status or rights pending
21 conclusion of review of, the challenged approvals, 5 U.S.C. § 705;
- 22 I. Waive any requirement of security under Federal Rule of Civil Procedure
23 65(c) in connection with any preliminary relief;
- 24 J. In the alternative, compel the agency action unlawfully withheld or
25 unreasonably delayed under 5 U.S.C. § 706(1), including the determinations
26 required by 21 U.S.C. § 360e(e);
27
28

1 K. Retain jurisdiction to ensure Defendants' compliance with the Court's
2 judgment, and require Defendants to file periodic status reports on their
3 compliance;

4 L. Award Plaintiffs their costs and reasonable attorneys' fees as permitted by
5 law, including under the Equal Access to Justice Act, 28 U.S.C. § 2412; and

6 M. Grant such other and further relief as the Court deems just and proper.
7

8 Dated: October 23, 2026

Respectfully Submitted,

9 /s/Behram V. Parekh

10 Behram V. Parekh (SBN 180361)

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1 **CERTIFICATE OF SERVICE**

2 I hereby certify that on October 23, 2026, I electronically filed the foregoing with the
3 Clerk of Court using the CM/ECF system and thereby served it on all counsel of
4 record.

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6 /s/Behram V. Parekh

7 Behram V. Parekh
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